type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2311, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 866.1620 Antimicrobial susceptibility test disc.

(a) *Identification.* An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc-agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.

(b) *Classification.* Class II (performance standards).

§ 866.1640 Antimicrobial susceptibility test powder.

(a) *Identification.* An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.

(b) *Classification.* Class II (performance standards).

§ 866.1700 Culture medium for antimicrobial susceptibility tests.

(a) *Identification.* A culture medium for antimicrobial susceptibility tests is a device intended for medical purposes that consists of any medium capable of supporting the growth of many of the bacterial pathogens that are subject to antimicrobial susceptibility tests. The medium should be free of components

known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.

(b) *Classification.* Class II (performance standards).

Subpart C—Microbiology Devices

§ 866.2050 Staphylococcal typing bacteriophage.

(a) *Identification.* A staphylococcal typing bacteriophage is a device consisting of a bacterial virus intended for medical purposes to identify pathogenic staphylococcal bacteria through use of the bacteria's susceptibility to destruction by the virus. Test results are used principally for the collection of epidemiological information.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 866.2120 Anaerobic chamber.

(a) *Identification.* An anaerobic chamber is a device intended for medical purposes to maintain an anaerobic (oxygen free) environment. It is used to isolate and cultivate anaerobic microorganisms.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 50823, Nov. 9, 1982, as amended at 66 FR 38790, July 25, 2001]

§ 866.2160 Coagulase plasma.

(a) *Identification.* Coagulase plasma is a device that consists of freeze-dried animal or human plasma that is intended for medical purposes to perform coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus *Staphylococcus* and provide epidemiological information on disease caused by these microorganisms.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38790, July 25, 2001]

§ 866.2170 Automated colony counter.

(a) *Identification.* An automated colony counter is a mechanical device intended for medical purposes to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 866.2180 Manual colony counter.

(a) *Identification.* A manual colony counter is a device intended for medical purposes that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and